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Practitioner's Docket No. U 014799-1

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application

of \_\_\_\_\_  
Inventor(s)

for \_\_\_\_\_  
Title of invention

OR

In re application of: Ken-Shwo DAI

Serial No.: 10/653,685

Group No.: 1645

Filed: September 2, 2003

Examiner.:

For: HUMAN SGII-RELATED GENE VARIANTS ASSOCIATED WITH CANCERS

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT  
WITHIN THREE MONTHS OF FILING OR  
BEFORE MAILING OF FIRST OFFICE ACTION (37 C.F.R. 1.97(b))

CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10\*  
(When using Express Mail, the Express Mail label number is mandatory;  
Express Mail certification is optional.)

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37 C.F.R. 1.8(a)

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Date: February 6, 2004

Signature  
CLIFFORD J. MASS  
(type or print name of person certifying)

\* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

NOTE: 37 C.F.R. 1.98(b):

- (1) Each U.S. patent listed in an information disclosure statement must be identified by inventor, patent number, and issue date.
- (2) Each U.S. patent application published listed in an information disclosure statement shall be identified by applicant, patent application publication number, and publication date.
- (3) Each U.S. application listed in an information disclosure statement must be identified by the inventor, application number, and filing date.
- (4) Each foreign patent or published foreign patent application listed in an information disclosure statement must be identified by the country or patent office which issued the patent or published the application, an appropriate document number, and the publication date indicated on the patent or published application.
- (5) Each publication listed in an information disclosure statement must be identified by publisher, author (if any), title, relevant pages of the publication, date, and place of publication.

**WARNING:** No extension of time can be had under 37 C.F.R. § 1.36 (a) or (b) for filing an IDS. 37 C.F.R. § 1.97(f).

**NOTE:** The "filing date of a national application" under 37 C.F.R. 1.97(b) has two possible meanings. Where the filing is a direct one to the United States Patent & Trademark office, the filing is defined in 37 C.F.R. 1.53(b) as "the date on which: (1) A specification containing a description pursuant to § 1.71 and at least one claim pursuant to § 1.75; and (2) any drawing required by § 1.81(a), are filed in the Patent and Trademark Office in the name of the actual inventor or inventors as required by § 1.41." 37 C.F.R. 1.97(b)(1). On the other hand, an international application that enters the national stage occurs when the applicant has filed the documents and fees required by 35 U.S.C. § 371(c) within the periods set forth in § 1.494 or § 1.495. 35 U.S.C. § 371(c) requires the filing of the following: (1) the national fee; (2) a copy of the international application, unless already sent by the International Bureau, and an English translation if filed in another language; (3) amendments under PCT Article 19, with a translation into English if made in another language; (4) an oath or declaration; and (5) a translation into English of any annexes to the international preliminary examination report, if such annexes were made in another language. 37 C.F.R. 1.97(b)(2).

### IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING INFORMATION DISCLOSURE STATEMENT

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. 1.97(b).

**NOTE:** "No certification or fee is due when the filing is made within the above time period. It is advisable to ensure that no Office action has been mailed if the disclosure statement is delayed until after three months from filing."

**NOTE:** "An information disclosure statement will be considered to have been filed on the day it was received in the Office, or on an earlier date of a mailing if accompanied by a properly executed certificate of mailing under 37 C.F.R. 1.8, or Express Mail certificate under 37 C.F.R. 1.10. An office action is mailed on the date indicated in the Office action." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

**NOTE:** "The term 'national application' includes continuing applications (continuations, divisions, continuations-in-part) so three-months will be measured from the actual filing date of an application as opposed [sic] to the effective date of a continuing application." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

**NOTE:** "An action on the merits means an action which treats the patentability of the claims in an application, as opposed to only formal or procedural requirements. An action on the merits would, for example, contain a rejection or indication of allowability of a claim or claims rather than just a restriction requirements (37 C.F.R. 1.142) or just a requirement for additional fees to have a claim considered (37 C.F.R. 1.16(d)). Thus, if an application was filed on Jan. 1 and the first Office action on the merits was not mailed until six months later on July 1, the examiner would be required to consider any proper information disclosure statement filed prior to July 1." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

**WARNING:** "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63).

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**SIGNATURE OF PRACTITIONER**

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**CLIFFORD J. MASS**

(type or print name of practitioner)

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Ken-Shwo DAI  
Serial No.: 10/653,685                      Group No.: 1645  
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Attorney Docket No.: U 014799-1

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Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Applicant respectfully calls the Examiner's attention to the information  
attached hereto and listed in the attached PTO Form 1449. Specifically, attached  
hereto are copies of: (a) a letter from Andrew Chin dated October 28, 2003 (received

**CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10\***

*(When using Express Mail, the Express Mail label number is mandatory;  
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**37 C.F.R. 1.8(a)**

**37 C.F.R. 1.10\***

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- ☐ transmitted by facsimile to the Patent and Trademark Office.

Date: February 6, 2004

Signature

CLIFFORD J. MASS  
(type or print name of person certifying)

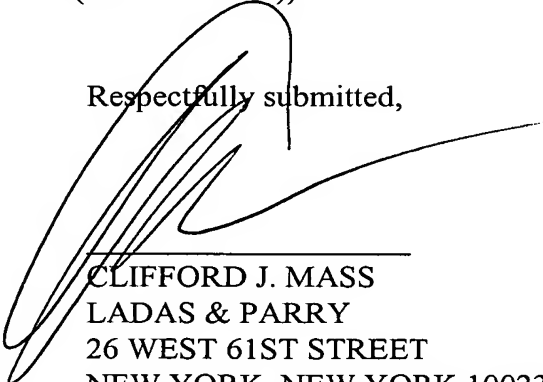
**\*WARNING:** Each paper or fee filed by "Express Mail" must have the number of the "Express Mail"  
mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b).  
"Since the filing of correspondence under § 1.10 without the Express Mail mailing label  
thereon is an oversight that can be avoided by the exercise of reasonable care, requests for  
waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed.  
Reg. 56,439, at 56,442.

November 4, 2003) calling our attention to a CD-ROM document produced by Dr. Chin entitled "On the preparation and utilization of isolated and purified oligonucleotides"; (b) a hard copy of the initial portion of the text file stored on the CD-ROM that was included with the letter; (c) a letter dated November 7, 2003 which the undersigned sent to the Kathrine R. Everett Law Library; (d) a letter dated November 11, 2003 from Anne Klinefelter of the Kathrine R. Everett Law Library to the undersigned; and (e) an online catalog record of Dr. Chin's CD-ROM that the undersigned recently found on the internet. Also attached hereto is a Computer readable form copy of the CD-ROM provided by Dr. Chin.

Applicant respectfully submits that the attached copy of the CD-ROM satisfies the provisions of 37 CFR 1.98(a)(2) for a legible copy of the information insofar as a computer readable form copy (and not a paper copy) is what has allegedly been deposited with the aforementioned law library. However, if it is considered that the applicable rule requires a computer readable form copy of the information, Applicant hereby petitions for a waiver of the rule and acceptance of the paper copy insofar as, according to Dr. Chin's letter of October 28, 2003, the CD-ROM contains several million oligonucleotides and acceptance of the computer readable form copy would facilitate both submission by the Applicant and consideration of the information by the USPTO. In the event a waiver of the rule is required, Applicant also hereby petitions for waiver of any petition fee insofar as the information is being submitted in connection with nineteen (19) applications of the Applicant and submission of a petition fee for each application would constitute an undue and unfair expense.

With respect to the weight, if any, that should be accorded the information, Applicant respectfully notes that, although it is alleged that the CD-ROM has been cataloged and shelved, it does not appear that the information has been indexed in any meaningful way that would make the information reasonably accessible to the public. In particular, the online catalog record of the CD-ROM, even assuming for the sake of argument that it was available online prior to the filing date of the present application, lists the title, author and subject, but this information does not provide the public with any indication as to what specific oligonucleotides, if any, might be disclosed in the CD-ROM or how to find any particular oligonucleotide that is disclosed. In fact, since the information in the CD-ROM has not been indexed in any meaningful way, the public would not have a ready way to find a particular oligonucleotide from among the millions of oligonucleotides present. Under these circumstances, it is respectfully submitted that the information was not reasonably accessible to the public such that the CD-ROM is not citable as a publication against the present application (see *In re Cronyn*, 13 USPQ 2d 1070, 1072 (Fed. Cir. 1989)).

Respectfully submitted,

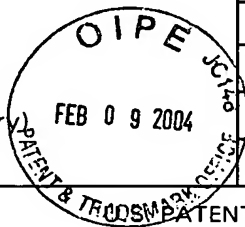


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FORM PTO-1449

U. S DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICEINFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(Use several sheets if necessary)



ATTY. DOCKET NO.

SERIAL NO.

U 014799-1

10/653,685

APPLICANT

Ken-Shwo DAI

FILING DATE

GROUP

September 2, 2003

1645

## REFERENCE DESIGNATION

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	FILING DATE IF APPROPRIATE
	AA				
	AB				
	AC				
	AD				
	AE				
	AF				
	AG				
	AH				
	AI				
	AJ				
	AK				

## FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
				YES	NO
	AL				
	AM				
	AN				
	AO				
	AP				

## OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)

	AR	"On the preparation and utilization of isolated and purified oligonucleotides" [electronic resource], Andrew Chin, allegedly deposited in UNC library on March 14, 2002, date of publication, if any, is in question.
	AS	
	AT	

EXAMINER

DATE CONSIDERED

EXAMINER:

Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.